Review Article

Accessibility and use of essential medicines in health care: Current progress and challenges in India

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ABSTRACT

Essential Medicine Concept, a major breakthrough in health care, started in 1977 when World Health Organization (WHO) published its first list. Appropriate use of essential medicines is one of the most cost-effective components of modern health care. The selection process has evolved from expert evaluation to evidence-based selection. The first Indian list was published in 1996 and the recent revision with 348 medicines was published in 2011 after 8 years. Health expenditure is less in India as compared to developed countries. India faces a major challenge in providing access to medicines for its 1.2 billion people by focusing on providing essential medicines. In the future, countries will face challenges in selecting high-cost medicines for oncology, orphan diseases and other conditions. There is a need to develop strategies to improve affordable access to essential medicines under the current health care reform.

Key words: Accessibility, essential medicines, health expenditures, India

INTRODUCTION

National health care system's major challenge is to provide appropriate health products and services in a reasonable, reliable and efficient manner accessible to majority of the population.[1,2] The World Health Organization's (WHO's) essential medicines list (EML) provides nations with a blueprint for selecting cost-effective and high-quality medicines.[2] At inception, in 1977 essential medicines (EMs) were defined as "medicines that are of utmost importance, and are basic, indispensable and necessary for the health needs of the population".[3] Since 2002, EMs are defined as "medicines that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy, safety and comparative cost-effectiveness. EMs are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of EMs is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility".[3] The key change has been in the process of selection from an expert-based approach to one that is evidence-based.

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NEED OF ESSENTIAL MEDICINE

Non-existence of national pharmaceutical policies and international criteria on ethical promotion and prescribing standards was a major constraint for the development of pharmaceutical growth in the early 1970s.[4] Majority of

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decolonized countries' health supply was struggling because of out of the range public budget due to importing branded drugs often of doubtful quality. World Health Assembly (WHA) was called upon then to improve this situation.[5] In 1970, first EML was prepared at a national level in Tanzania.[6] This was followed by WHA resolution WHA 28.66 in 1975 by which WHO was called on to assist member states to select and procure essential drugs of good quality in a cost-effective manner.[4] A review started in 1966, found that about 66% of the 3,000 marketed drugs were not effective.[7] This led the director general of WHO to provide a report to WHO governing body in 1975 describing the drug problems faced by national health services in countries with few resources.[7] Finally in 1977, WHO compiled its first EML. EMs was 1 of the 8 key components proposed for primary healthcare at the 1978 Alma Ata conference.[6]

WHO MODEL LIST OF ESSENTIAL MEDICINES

The WHO model list focuses on medicines that address conditions that create the greatest public health threat with an emphasis on common infections and chronic diseases.[8] The model EML serves as a guide to develop country's own national EML.[9] Since its inception, the list has been updated every two years and the current list is the 17th (2011) WHO EML [Figure 1]. The list consists of a core list (efficacious, safe, and cost-effective medicines for priority conditions) and a complementary list (priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training is needed).[13] The current list contains 445 medicines and 358 molecules excluding duplicates (347 molecules in core list and 98 in complementary list). It is composed of 871 formulations and dosage forms. WHO has also incorporated EML for children from 2007 and the latest 3rd (2011) revision consists of 269 drugs.[14]

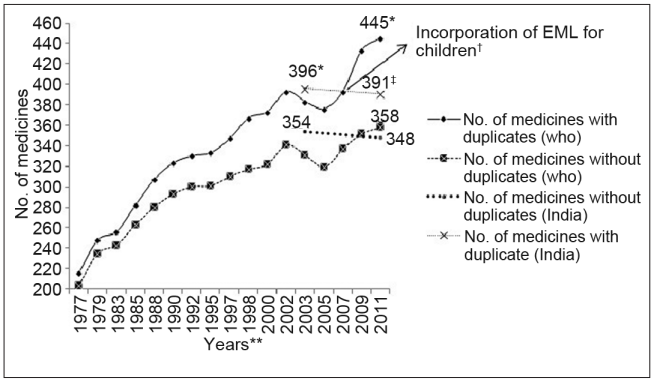

Figure 1: Trends in WHO[10] and Indian EML[11,12] *Including core and complementary medicines †WHO incorporated EML for Children (EMLc) from 2007 and the latest 3rd (2011) revision consists of 269 medicines ‡No complementary medicines are listed in the current EML **WHO has introduced its first EML in 1977 but India has introduced its NEML in 1996 with two revisions in 2003 and 2011

The most significant addition to the WHO Model List has been the EML for Children (EMLc) from 2007 and the latest 3rd (2011) revision consists of 269 drugs.[14] Medicines used by adults are not suitable for children and need special adjustments in the dosage, formulation and delivery. The EMLc was integrated into the WHO Model List for adults, although a separate list is also maintained. New symbols were introduced to indicate medicines with a restricted indication for use in children, when specialist care was needed in the treatment of children with the medicine and any age restriction. Two new sections were also added for medicines for the treatment of ear, nose and throat conditions in children and specific medicines for neonatal care.

WHO essential medicine library is a web-based information service and provides access to model list, disease/indication information and model formulary. It is available on website and CD-ROM, and in print.[15,16]

Drivers and advantages of selection of EMs

Over the years, the selection criteria has changed from experience-based to evidence-based.[6] Selection of drugs for inclusion in EML depends on their relevance to public health, safety, clinical efficacy, total cost and relative cost-effectiveness.[17] Rising price of a medicine is not a reason to exclude it from the list if other stated selection criteria are being met.[18] Choice may be influenced by pharmacokinetic properties or storage facility for the manufacturer. Fixed dose combinations (FDCs) are selected only when the combination has proven advantageous in therapeutic effect, safety, adherence or in decreasing the emergence of drug resistance like in malaria, tuberculosis and HIV/AIDS.[15] The current WHO model EML has 23 FDCs. WHO has published reports of the WHO expert committee on the selection and use of EMs every two years with current "WHO Technical Report Series 958 incl. Children, 2009."[19]

Careful selection of a limited range of essential medicines results in higher quality and cost-effective use of health resources.[20] It has also improved procurement, storage, distribution and dispensing of drugs.[8]

National essential medicines list and India

According to WHO expert committee essential drugs programs were intended to be adapted and to be appropriate for the particular national setting depending on prevalence pattern of disease and available new medicines.[7,21] Medicines listed in national standard treatment guidelines (STG) should be given preference for inclusion in NEML.[22] NEML, together with STG, should serve as the basis for formal education, in-service training of health professionals and public education about the medicine use. WHO survey 2007 has shown that at least 134 countries have their NEML. The majority had been updated in the previous five years.[22] The

number of medicines included in the NEML varies, with a global median of 397 (334-580).[22]

EM concept is somewhat new to India. Tamil Nadu was the first state to develop EML in 1994.[9] The Delhi state drug policy was adopted in 1994. The first NEML was prepared in 1996.[23] This list was neither implemented for procuring drugs nor STGs were drawn up.[24] The first and second revision was published in 2003 and 2011, respectively. NEML 2011 was revised based on the Indian Pharmacopeia 2010 and the National Formulary of India, 4th edition, 2010. The workshop entitled "Expert Group Meeting on Revision and Updating of the National List of Essential Medicines" was organized in September 2009 and the first meeting of core committee was held at CDSCO in July 2010. Further two meetings of core committee at CDSCO in 2011 resulted in NEML 2011. Unlike WHO EML and 2003 edition of Indian EML, there is no provision of complementary list in the current edition. NEML 2003 had some complementary medicines included in the core list itself. The current list is also divided according to various levels of medical care. The Government of India, Ministry of Health and Family Welfare (MOHFW) is responsible for preparing the EML.[11] The current 3rd edition (2011) has 348 medicines and 653 formulations and dosage forms. Forty-seven drugs included in the previous list have been removed and 43 new drugs are being added in the current list.[11] It contains 14 medicines for HIV/AIDS and 33 oncology medicines. There is a difference in the number of drugs according to WHO Anatomical Therapeutic Classification (ATC) between WHO and NEML of India [Figure 2]. India doesn't have a separate list for children. However, Indian Academy of Pediatrics (IPA) has published EML for children in 2011 (1st edition) with 134 medicines.[26]

EMs to promote rational use of drugs

The more drugs available for an indication, the more complex is the decision and potentially, the less rational is the choice. Thus selected safe, efficacious and cost-effective essential drugs decrease the complexity of prescribing drugs and will promote RUD.[27] Because prescribers need to know about fewer drugs, they can have a better understanding of the drugs they do prescribe.[27] "Development and use of NEML" is one of the key interventions to promote RUD.[28] Worldwide more than 50% of all medicines are prescribed, dispensed or sold inappropriately, while 50% of patients fail to take them correctly.[29] Most leading causes of death, disease and disability in developing countries can be prevented, treated or at least alleviated with cost-effective EMs.[30] RUD is defined as "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." In India some of the internationally discarded drugs like analgin, nimesulide, nitrofurazone, etc., are allowed to be marketed [Table 1][30]. However, the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is working since 1996 for promoting RUD.[32]

Delhi model for improving access to medicines

In 1994, medicine supply was irregular and uncoordinated in government hospitals and dispensaries. An EML committee drew up a common list of 250 EMs for hospitals and 100 medicines for dispensaries to overcome this problem. STGs for most commonly occurring problems in adults and children were also issued at primary health care centers. Usage of these medicines by the hospitals run by Delhi government resulted in a sharp fall in procurement prices and a 30% saving in annual medicine bill. These savings led to more than 80% availability

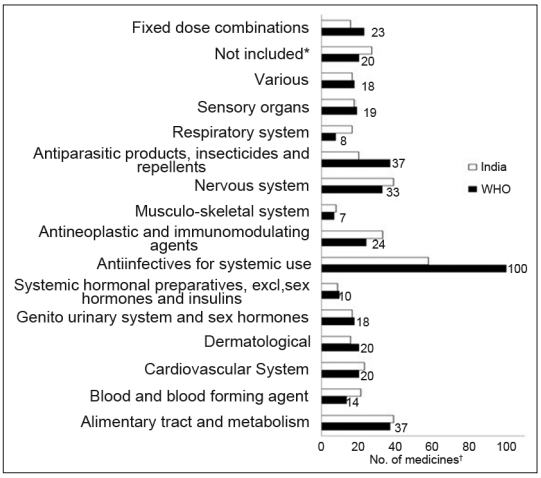

Figure 2: ATC Classification[25] of drugs in WHO EML (2011) and India EML (2011) *Items that are not included in ATC classes (e.g., coal tar, calamine, cryoprecipitate, etc.) †Total number of medicines is more than that of present in EML because some drugs are categorized in more than one class

Table 1: Drugs that are banned worldwide but allowed to market in India[31]

Name of drug	Use	Reason for withdrawal
Metamisol (Analgin)*	Analgesic	Agranulocytocis
Oxyphenbutazone*	Analgesic	Bone marrow depression
Nimesulide†	Analgesic	Liver toxicity
Furazolidone‡	Antidiarrheal	Risk of cancer
Nitrofurazone**	Antidiarrheal	Risk of cancer
Cerivastatin	Dyslipidemia	Rhabdomylosis
Phenolphthelin	Stimulant purgative	Risk of cancer
Quiniodochlor	Amoebicidal	Subacute myelo-optic neuropathy
Thioridazone	Antipsychotic	Arrhythmia
Pergolide	Parkinson's disease	Damage to heart valves
Droperidol	Antidepressant	Irregular heartbeat (cardiac arrhythmia)

*Fixed dose combinations of these drugs are banned but drug alone is allowed to market. †Banned for use in children. ‡Combination of furazolidone and loperamide is banned. **Combination of nitrofurazone and trimethoprim is banned. §Drugs are not included in the list of "Banned drugs in India"

of medicines at health facilities. Positive changes were also seen in the prescribing behavior.[8,33,34]

Availability, accessibility and affordability of medicines

Availability and affordability are key components in equitable access to EMs.[35] Fifty to eighty percent Indian population has limited access to EMs.[36] A study conducted in 36 developing and middle income countries has shown poor availability of generics in public sector as compared to private sector.[37] In over 40 low-income countries 44% of public sector and 65% of private sector outlets had the listed generic medicines in stock. Lack of medicines in the public sector forces patients to go without or purchase medicines from private sector outlets where generic medicines cost on average 6 times more than their international reference price, while originator brands are generally even more expensive.[38] WHO reported that one third of the world's population lacks reliable access to required medicines and the situation is even worse in developing countries.[39] Poverty and unavailability of EMs can be the cause of more than 18 million deaths, which could be prevented.[40] The medicine cost is not always the constraint for the affordability in the society.[41] Drugs cost 25-66% of the health budgets in developing countries, equal to 20% of health budgets in industrialized countries.[17] Despite having lower prices of medicines in India as compared to the international prices, the availability and affordability is poor.[42] The findings of one study suggested that access to EMs as a part of the fulfillment of the right to health could indeed be enforced through the courts.[43]

Health expenditures

Health expenditures vary being as high as 18% of GDP in U.S. to as low as 2% of GDP in Myanmar in 2010 [Table 2]. In India both health expenditure as percentage of GDP and public spending as percentage of total health expenditure is low when compared to developed countries.[46]

In U.S. the total health expenditure has been increasing from 13.6% in 1995 to 16.2% in 2009.[47] For India health expenditure remains more or less the same, it was 4.11% in 1995 and 4.2% in 2009.[48] The share of public expenditure in GDP has increased consistently during 2005-06 (0.96%) to 2008-09 (1.10%).[49] The trend of spending on pharmaceuticals is decreasing as the total expenditure on pharmaceuticals was 40.9% of the total expenditure on health in India in 2009 while it was 44.2% and 45.3% in 2008 and 2007, respectively.[48] In India the drug expenditure also varies state-wise [Figure 3]. Among the major states the total health expenditure per capita was as high as Rs. 2,950 in Kerala and as low as Rs. 513 in Bihar.[46] The availability of medicines in India is still a big issue. The availability of medicine is influenced by several factors like poor medicine supply, insufficient health facilities and staff, low investment in health and affordability.[9]

WHO's achievements after 30 years of essential medicine list

In 1977 only about 12 countries had an EML or essential drugs program. More than 100 countries have national drug policies now in place or under development, which was not known previously. The concept of RUD was very much limited especially in developing countries. After 30 years at least 135 countries have their own therapeutic manuals and formularies, which provide accurate information on the rational use of drugs. In 1977, the WHO program for International Drug Monitoring was just being formally established. Currently 83 countries are involved in global monitoring of adverse drug reactions and regularly pick up signals on potential safety problems.

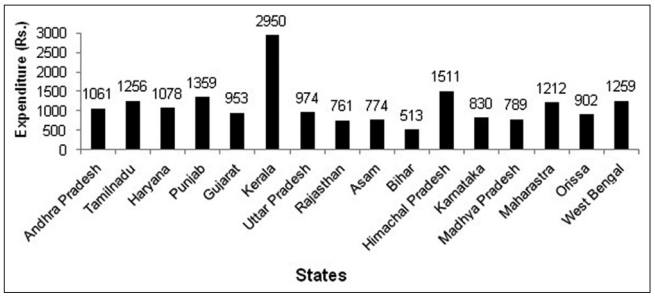

Figure 3: State-wise health expenditure in India (2004-2005) (Source: National health accounts of India 2004-2005)[49]

Table 2: Health spending by countries and current EML (US and South East Asian Region of WHO)

Country	Total expenditure on health as % of GDP* (2010)	Total expenditure on health per capita (Intl $, 2009)	General government expenditure on health as % of total health expenditure (2010)	Private expenditure on health as % of total health expenditure (2010)	Current EML
USA	18	7417	53	47	Not present
Timor-Leste	9	120	56	44	2004
Maldives	6	412	60	40	2009
Nepal	6	69	33	67	2009
Bhutan	5	274	87	13	2009
Thailand	4	345	75	25	2008
India	4	132	29	71	2011
Sri Lanka	3	193	45	55	2009
Bangladesh	3	48	34	66	2008
Indonesia	3	99	49	51	2008
Myanmar	2	23	12	88	2010

*GDP=Gross domestic product. (Source: Country reports of WHO and global health expenditure database)[44,45]

Virtually, price information was not available to public. Only some countries preferred generic prescribing. After 30 years, at least 33 countries have collected information about availability and pricing surveys and provide that information to public. In addition, the wider use of quality assured generic medicines since the 1990's have brought down prices through increased demand and competition.[50]

Disadvantages/Problems with essential medicines list

Selection of limited numbers of essential medicines delay the inclusion of new medicines until the selection group meets and decides to include in the list.[27] It will also limit the ability of physicians to prescribe drugs not in specific EML.[27] EML will harm the research and development activities since sponsors won't be afraid about new medicine's market potential but because of its exclusion from the list.[27] Inclusion of a medicine in EML does not give surety about availability at all public hospital and clinics all the time.[34] EML does not give information about funding of purchasing and procuring the products.[34]

India's perspective

The current list (2011) has been revised after 8 years. Like WHO EML, regular revisions are necessary at least once in 2 years. National Drug Policy has also been enacted since 1979 with current draft of National Pharmaceutical Pricing Policy 2011.[51] The concept of RUD is well accepted by the country and DSPRUD is working to promote it.[32] India is one of the member countries of WHO program for international drug monitoring (WHO-UMC) and information from India are being sent to Uppsala Monitoring Centre.[52] India introduced its own Pharmacovigilance Program in 1997[53] with its third round functioning since 2010.[52] It aims to recruit 300 ADR monitoring centers by 2015. Indian WHO/Health Action International has developed a standardized survey methodology for measuring medicine prices, availability, affordability and price components.[54] In India, these surveys have been done in states like Maharashtra[35] and West Bengal.[55] However, there is a need of such survey being conducted at national level. WHO has also published "The Interagency List of Essential Medicines for Reproductive Health (2006)" for current international consensus on rational selection of essential reproductive health medicines.[56] It is important to emphasize on reproductive health medicines in NEML of India. Complementary medicines list should also be maintained at various levels of health care. There is also a need to incorporate the concept of EML for children in India as pediatric population comprises 31% of the total population of India.

India is reckoned among the global leaders in manufacturing generic medicines. However, it is also held that large population is without having access to basic medicines. Implementation of NEML in procurement of good quality medicines, regular supply as well as price regulation, strengthening indigenous manufacturing capacity should be emphasized. In the end, regular and widespread accessibility of EMs needs to be ensured to enhance the credibility of health care system.

CONCLUSION

In conclusion, the essential drugs concept introduced since 1975 is now widely accepted as a highly pragmatic approach to provide the best of modern, evidence-based and cost-effective health care. The challenge is to regularly update drug selections in the light of new therapeutic options, changing therapeutic needs, the need to ensure drug quality and continued development of better drugs, drugs for emerging diseases and drugs for coping with changing resistance patterns. There is also a need to fill gaps in availability, accessibility and affordability of medicines to the poor.

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